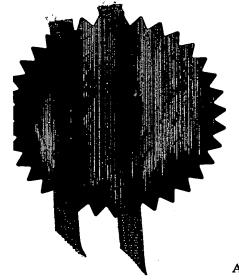
			Rec'd FO/PTO 07 SEP 2004 10/500999 INVESTOR IN PEOPLE
-	PRIORITY DOCUMENT SUBMITTED OR TRANSMITTED IN COMPLIANCE WITH RULE 17.1(a) OR (b)	EPO - DG 2 4. 06. 20	Newport
-	·	48)	REC'D 0 8 JUL 2003 WIPO PCT

I, the undersigned, being an officer duly authorised in accordance with Section 74(1) and (4) of the Deregulation & Contracting Out Act 1994, to sign and issue certificates on behalf of the Comptroller-General, hereby certify that annexed hereto is a true copy of the documents as originally filed in connection with the patent application identified therein.

In accordance with the Patents (Companies Re-registration) Rules 1982, if a company named in this certificate and any accompanying documents has re-registered under the Companies Act 1980 with the same name as that with which it was registered immediately before re-registration save for the substitution as, or inclusion as, the last part of the name of the words "public limited company" or their equivalents in Welsh, references to the name of the company in this certificate and any accompanying documents shall be treated as references to the name with which it is so re-registered.

In accordance with the rules, the words "public limited company" may be replaced by p.l.c., plc, P.L.C. or PLC.

Re-registration under the Companies Act does not constitute a new legal entity but merely subjects the company to certain additional company law rules.



Stephen Hordby. Signed

Dated 8 April 2003

BEST AVAILABLE COPY

An Executive Agency of the Department of Trade and Industry

Patents Form 1/77	The	
ents Act 1977	Patent 1/"	
(Rule 16)		
ſ	Office	
/	THE PATENT OFFICE	
	2 N KIN 20HAR02 E705155-1 C69803	
Request for grant of a patent	P01/7700 0.00-0206560.5	
(See the notes on the back of this form. You can also get an explanatory leaflet from the Patent Office to help	i i i i i i i i i i i i i i i i i i i	
you fill in this form)	New ORT Ne	
1. Your reference	Gwent NP	
	RFW/EB/C70501	
2. Patent application number		
(The Patent Office will fill in his part)	0206560.5	
	0200500.5	
3. Full name, address and postcode of the or of		
each applicant (underline all surnames)	Glaxo Group Limited	
	Glaxo Wellcome House, Berkeley Avenue	
Patents ADP number (if you know it)	Greemord, Middlesex UB6 ONN, Great Britain	
If the applicant is a corporate body, give the	473587003	
country/state of its incorporation	United Kingdom	
4. Title of the invention		
	Novel Device	
5. Name of your agent (if you have one)		
	Corporate Intellectual Property	
"Address for service" in the United Kingdom to which all correspondence should be sent	GlaxoSmithKline	
(including the postcode)	Corporate Intellectual Property CN925 1	
·	980 Great West Road	
Patents ADP number (if you know it)	BRENTFORD Middlesex TW8 9GS 807255500	
6. If you are dealer in the		
6. If you are declaring priority from one or more earlier patent applications, give the country	Country Priority application number Date of filing	
and me date of thing of the or each of	(if you know it) (day / month / year)	
ulese earlier applications and (if you know it) the		
or each application number		
7. If this application is divided or otherwise		
derived from an earlier UK application	Number of earlier application Date of filing	
give me number and the filing date of	(day / month / year)	
the earlier application		
8. Is a statement of inventorship and of right	· · · · · · · · · · · · · · · · · · ·	
to grant of a patent required in support of		
this request? (Answer yes if:		
The second standard yes y.		
 a) any applicant named in part 3 is not an inventor, or b) there is an inventor who is named as an applicant, or c) any named applicant is a corporate body 		

Patents Form 1/77



>. Enter the number of sheets for any of the following items you are filing with this form. Do not count copies of the same document

Continuation sheets of this form

14 hr 6 hr 75 only /

Description Claim(s) Abstract Drawings -

10. If you are also filing any of the following, state how many against each item.

Priority Documents

Translations of priority documents

Statement of inventorship and right to grant of a patent (Patents Form 7/77)

Request for preliminary examination and search (Patents Form 9/77)

Request for substantive examination (Patents Form 10/77)

> Any other documents (please specify)

11.

We request the grant of a patent on	the basis of this
application Ration	Date 19-Mar-02
P F Walker	

C 41 . : -

.

12. Name and daytime telephone number of person to contact in the United Kingdom R F Walker 020 80474485

Warning

After an application for a Patent has beeen filed, the Comptroller of the Patent Office will consider whether publication or communication of the invention should be prohibited or restricted under Section 22 of the Patents Act 1977. You will be informed tf it is necessary to prohibit or restrict your invention in this way. Furthermore, if you live in the United Kingdom, Section 23 of the Patents Act 1977 stops you from applying for a patent abroad without first getting written permission unless an application has been filed at least six weeks beforehand in the United Kingdom for a patent for the same invention and either no direction prohibiting publication or communication has been given, or any such direction has been revoked.

Notes

- a) If you need help to fill in this form or you have any questions, please contact the Patent Office on 0645 500505
- b) Write your answers in capital letters using black ink or you may type them.
- c) If there is not enough space for all relevant details on any part of this form, please continue on a separate
- sheet of paper and write "see continuation sheet" in the relevant part(s). Any continuation sheet should be attached to this form.
- d) If you have answered 'Yes' Patents Form 7/77 will need to be filed.

1

The present invention relates to injection devices, in particular to needle-less injection devices in which a compressed gas cartridge is used to force a jet of medicament through a patient's skin. Specifically, this invention relates to a casing for such an injector device which interacts with the safety mechanisms of such an injection device.

Injection devices generally comprise a number of elements. Generally there is a cartridge of a medicament having a nozzle orifice at one end, out of which in the case of a needle-less injection device the medicament is driven under a pressure

- 10 sufficient to drive it through a patient's skin. Generally there is a drive means to drive the medicament in this manner, typically comprising a plunger moveable within the cartridge toward the nozzle orifice to drive the medicament, and a means to drive the plunger, such as a spring, commonly comprising a spring means such as compressed gas driving a ram which bears upon the plunger. Generally there is a trigger means
- 15 operable to cause the drive means to act. Often there is a safety device to prevent the drive means from being inadvertently operated, for example by preventing the trigger means from operating. The cartridge of medicament may for example comprise a dose of liquid or powdered medicament to be administered to the patient. Sometimes in a needle-less injection the nozzle orifice of the cartridge is closed prior to use by a
- 20 break-off tip. Often the drive means, cartridge and orifice lie along an elongate direction which corresponds to the direction along which the plunger moves and the medicament is dispensed.

Needle-less injection devices of various types are described in, inter alia, published International Patent Application Nos. WO93/03779 and WO95/03844 (Weston Medical Limited).

Published International Patent Application No. WO97/37705 (Weston Medical Limited), the contents of which are incorporated herein by reference, discloses a needle-less injection device of the general type described above in which compressed gas in a cylinder 130 drives a ram 111 which bears upon a plunger 104 which is moveable within a medicament cartridge 103 to drive medicament content out through orifice 106. In the device of WO97/37705 firing of the device is prevented by a latch 108 which obstructs the ram 111 and must be moved sideways to allow the ram 111 to move. A trigger means is provided by the device comprising upper 102a and lower 102b relatively moveable sleeve portions, and in its pre-firing

30

25

configuration the sideways movement of the latch 108 being obstructed by the wall of the upper sleeve 102a. The upper 102a and lower 102b sleeves are moved relative to each other by placing the lower sleeve 102b against the user's skin and urging the upper sleeve downwardly. The relative movement of the upper 102a and lower 102b sleeve portions brings an aperture 139 in the wall of the upper sleeve portion 102a into alignment with the latch 108, allowing the latch to move sideways into the aperture 139 so that it no longer obstructs the ram. A cam surface 109 on the ram 111 bears on the latch 108 under the force exerted by the compressed gas and forces the latch sideways into the aperture 139.

10

5

5

In the device of WO97/37705 a safety mechanism is provided by a tear-off band 137 situated between the upper 102a and lower 102b sleeve portions to obstruct the said relative movement of these sleeve portions until the band 137 has been torn away.

In the device of WO97/37705 the nozzle orifice of the cartridge is closed prior to use by a break-off tip 135 which comprises a seal carrier which carries a seal 134.

However, various problems may arise from the handling and use of a device such as that of WO97/37705 and similar devices. For instance, the device is fragile and may not be robust enough to be transported by a user in, for instance, a handbag or a pocket. Furthermore, the user may perform the steps required for the actuation of

20 the device in the wrong order. The device of WO97/37705 must be actuated by first snapping off the seal carrier 135 and then removing the tear-off band 137, before urging the orifice 106 against the user's skin. If the user mistakenly removes the tear-off band 137 before snapping off the seal carrier 135, it is possible that the action of snapping off the seal carrier may cause the device to be inadvertently actuated. This would result in a wasted dose of the medicament and possibly even delivery of the medicament into the wrong site (e.g. the user's hand).

Also, once the device has been used, the user must dispose of the device and the parts that have been removed, i.e. the seal carrier 135 and the tear-off band 137, in a safe manner so that the user herself or other people, for instance children, are not endangered by loose parts of the actuated device.

30

Also, in the device of WO97/37705 there is a risk that a weak user may not be able to apply sufficient force to break the break-off seal 135 at the frangible joint 136, or the break-off force may be applied unevenly e.g. resulting in inadequate opening of

possession with the broken-off carrier 135, potentially with sharp edges around the frangible join 136.

3

An object of the present invention is to provide an improved injection device, particularly an improvement to the device of WO97/37705, providing a solution to at least some of the aforementioned problems.

Thus, according to a first aspect the present invention provides a casing for an injector device of the type which comprises a cartridge containing a medicament for injection and having an orifice at one end thereof through which the medicament may be driven for injection through a patient's skin, drive means for driving the

10 medicament through the patient's skin, a trigger means operable to cause the drive means to act, a safety means which in a first configuration prevents the drive means from acting and in a second configuration allows the drive means to act,

wherein

the casing is able to enclose the device,

and the casing incorporates an actuator means by which the safety means of an injector device enclosed therein can be brought from its first configuration into its second configuration.

The casing of the present invention facilitates the use of an injector device, in particular in its preferred embodiments by causing the user to operate the injector device according to its pre-determined operating sequence. As secondary advantages the casing can protect the enclosed injector device, improve its aesthetic appearance and improve user compliance by making the injector device appear less intimidating.

Preferably the actuator means may be accessed by a user from outside the casing, so that the user can actuate, i.e. bring from its first configuration into its second configuration, the safety means of an injector device enclosed therein from outside the casing.

In one form for example, the actuator means may have a part exposed to the outside of the casing and accessible to the user, and to which the user may apply operating force to actuate the safety means.

For example such an actuating means may be constructed to bear upon the safety means and thereby apply actuating force to the safety means to bring it from its first configuration into its second configuration.

15

5



For example the actuator means may comprise a button, tongue or lever which the user may press inwardly to cause the actuator means to bear upon the safety means and thereby bring it from its first configuration into its second configuration.

4

For example the actuator means, particularly such a button, tongue or lever, may be resiliently connected to the casing such that on application of actuating force to the actuator means, the actuator means operates against the resilient bias.

For example the actuator means may be constructed so that after it has brought the safety means from its first configuration into its second configuration, the actuator means may give a visible indication that this has happened. For example the actuator means may remain locked in a visibly deflected position.

Preferably the casing has retaining means to retain the safety means of an enclosed device in its second configuration after the safety means has been brought from its first configuration into its second configuration.

In another form, for example the actuator means may comprise a window in the casing through which the safety means may be actuated. For example such a window may be so shaped and positioned that a user may be able to reach the safety means of an injector device enclosed therein, or so that a part of the safety means of an injector device enclosed therein may extend through the window to be accessed and operated by the user from outside of the casing.

By "enclosed" is included partial or complete enclosure. Preferably the casing is adapted to enclose at least the cartridge, the drive means, the trigger means and the safety means of the injector device. Preferably the casing has an opening, which may be removably covered prior to use, by which the orifice through which the medicament may be driven for injection through a patient's skin can be brought adjacent to the patient's skin. In an elongate casing such an opening may be an end opening.

Preferably the casing has internal supports able to securely hold an injector device enclosed therein. The design of these will depend upon the shape and construction of the injector device to be enclosed. If the casing is to hold a device

30 such as that of WO9737705 which is triggered by being pressed against a user's skin, it is important that the casing is constructed such that pressure applied to the casing to press the device against the user's skin is communicated to the injector device, and such supports may be used to achieve this.

20

5

10

A second aspect of the present invention provides a combination of a casing as described above according to the first aspect, and enclosed within the casing an injector device of the type which comprises

5

a cartridge containing a medicament for injection and having an orifice at one
end thereof through which the medicament may be driven for injection through a patient's skin, drive means for driving the medicament through the patient's skin, a trigger means operable to cause the drive means to act, a safety means which in a first configuration prevents the drive means from acting and in a second configuration allows the drive means to act.

10

Preferably in its first configuration the safety means prevents the drive means from acting by preventing the trigger means from operating, for example by obstructing the movement of a moveable trigger part, and in its second configuration allows the trigger means to operate.

Therefore preferably the safety means comprises an obstructer part which in the first configuration obstructs, and in the second configuration allows, the movement of a moveable trigger part.

Such a safety means may be moveable, by using the actuator means, from its first configuration to its second configuration, e.g. the actuating means may bear upon the safety means and thereby apply actuating force to the safety means to move it.

When the casing is elongate, preferably a moveable safety means comprises an obstructer part which is brought from its first configuration to its second configuration by a movement of the obstructer part, or the entire safety means, in a direction perpendicular to the elongate direction.

For example a moveable safety means may comprise a collar shaped to at least partly surround the injector device, and moveable from its first configuration into its second configuration in a direction generally perpendicular to the direction in which the medicament is dispensed, the collar incorporating an obstructer part.

Preferably the safety means, or at least the obstructer part, is biased to be retained in its first configuration and is movable against this bias into its second configuration.

For example a moveable safety means may comprise a removable obstructer part, e.g. a tear-off band functioning as an obstructer part as disclosed in WO97/37750, and such a band may have an extension which is accessible from

20

outside of the casing, e.g. through a window in the casing, which a user may grip and pull to remove the obstructer part from the injector device and from the casing.

6

Alternatively the safety means may be broken or destroyed in its second configuration, e.g. the actuating means may bear upon the safety means and thereby apply actuating force to the safety means to break or destroy it.

Preferably the injector device is as disclosed in WO97/37705 the content of which is incorporated herein by reference.

Therefore preferably the trigger means, as in WO97/37705, is provided by two relatively moveable upper and lower sleeve parts which on relative movement allow the drive means to act.

When the injector device comprises a device in which the trigger means comprises two relatively moveable upper and lower sleeve parts which on relative movement allow the drive means to act, the safety means may comprise an obstructer part which in its first configuration obstructs, and in its second configuration allows,

15 the relative movement of these sleeve parts.

5

10

20

25

For example with such a device preferably the safety means comprises an obstructer part which is brought from its first configuration to its second configuration by a movement of the obstructer part in a direction perpendicular to the direction of relative movement of these two sleeves, this direction suitably being perpendicular to the elongate direction of the device and the casing, being also generally perpendicular to the dispensing direction of the medicament.

For example when the injector device comprises a device in which the trigger means comprises two relatively moveable upper and lower sleeve parts which on relative movement allow the drive means to act, as in the device of WO9737705, such a moveable safety means may comprise a collar shaped to at least partly surround the injector device, and moveable from its first configuration into its second configuration in a direction perpendicular to the direction of relative movement of these two sleeves, the collar incorporating an obstructer part which in the first configuration is situated between the two sleeves to obstruct the relative movement, and in the second

30 configuration is displaced in a direction perpendicular to the direction of relative movement of these two sleeves to thereby allow the relative movement of these sleeves.

Such a collar may surround that part of the injector device longitudinally

configuration, for example by spring parts bearing upon the injector device or upon the casing, so that movement into the second configuration is against this bias.

7

Preferably the safety means, e.g. a collar as described above, has retaining means by which it may be retained in its second configuration after the safety means has been actuated. Such retaining means may interact, e.g. lock with, corresponding retaining means on the casing or the injector device.

Alternatively the safety means may require a continuous actuation of the actuator means to retain the safety means in its second configuration.

Such a safety means, e.g. the above described collar, may be integrally made of resilient plastics materials.

A third aspect of the present invention provides a casing for enclosing a container of a medicament of the type having an opening at one end through which the medicament may be accessed for dispensing and the opening being closed prior to use by a break-off tip,

the casing comprising relatively moveable first and second casing parts, being a first casing part adapted to hold the container, and a second part adapted to bear upon the break-off tip of a container held by the first casing part as a result of such relative motion to apply a force thereto causing the break-off tip to break off from the container.

Preferably the container is an injection device of the type comprising a cartridge having its injection nozzle orifice closed prior to use by a break-off tip.

In one embodiment the first casing part may be elongated along a longitudinal axis, the first casing part may be adapted hold the container non rotatably relative thereto, e.g. by internal supports and the second part may move in rotary motion relative to the first part so as to bear on the break-off tip of a container held by the first casing part, and to apply a twisting shearing force to the frangible joint between the break-off tip and the container.

Such rotary relative motion may be about a rotation axis coaxial with this longitudinal axis, about a rotation axis parallel to but non-coaxial with this

longitudinal axis, or about a rotation axis at a non-zero angle to the longitudinal axis. The latter two modes of rotary motion may be advantageous in applying a shearing force to the frangible joint.

For example such rotation may be achieved by means of the first and second casing parts being initially connected together by a screw thread connection, so that

15

20

25

30

10

5

ř.

unscrewing the connection applies a shear force to break off the tip of a container held by the first casing part, and also separates the first and second casing parts to hereby expose the opening for use.

8

Alternatively such rotary relative motion may be about a rotation axis transverse to e.g. preferably perpendicular to this longitudinal axis so as to snap the frangible joint. For example such rotation may be achieved by the second casing part being pivotally mounted on the first casing part, with a pivot axis perpendicular to the longitudinal axis.

The second casing part may have internal parts to hold or support the break off 10 tip, and/or which bear on the break off tip during the relative motion. The second casing part may be internally provided with gripping means to assist the second casing part in bearing on the break-off tip of a container held by the first casing part, and applying the shearing force. The design of these will depend upon the shape and construction of the injector device to be enclosed.

For example the second casing part may incorporate a cup part having internal surfaces of a rubbery material with a high coefficient of friction relative to the breakoff tip.

In a preferred embodiment the casing of this third aspect of the invention is a casing of the first aspect of the invention, which may be used in a combination as in the second aspect of this invention, and the first casing part is adapted to hold an injector device wherein the cartridge has an opening at one end through which the medicament may be dispensed and the opening is closed prior to use by the break-off tip.

Preferably for use with such an injector device the first casing part may be elongated in the longitudinal direction along which the plunger moves to drive the medicament through the orifice.

Preferably when the first casing part is adapted to hold an injector device the first casing part has an opening by which the orifice through which the medicament may be driven for injection through a patient's skin can be brought adjacent to the patient's skin, and this opening may be an end opening of an elongate first casing part. and the second casing part comprises a removable cover for this end opening.

30

e.g. in the form of an end cap.

In this preferred embodiment, the casing may be constructed so that the

relative to the first casing part in the manner described above. This can ensure that an injector device contained therein is operated in the correct operating sequence, i.e. the break-off tip is first broken off and only thereafter the drive means can be caused to operate.

9

For example the second casing part may comprise a cover part over the actuator means which prevents operation of the actuator means until the cover part is removed. For example the second casing part may comprise a cap, covering the actuator, with a screw thread connection to the first casing part and the action of unscrewing such a cap may both break off the break-off tip and expose the actuator for use.

Alternatively the second casing part may incorporate a locking means to lock the actuator means until the second casing part has been removed.

The casing of all aspects of the invention, and the safety means such as a collar, may conveniently be made of plastics materials by for example injection moulding

15 moulding.

The invention also provides a combination of such a casing and an injector device enclosed therein.

Preferred features of such a casing, and its combination with an injector device, are as described above.

The construction and operation of a device according to this invention will now be described by way of example only with reference to the following Figures.

Figs. 1-4 show schematically the operation of a known type of needle-less injector device.

Figs. 5-8 show schematically the construction of a casing of this invention and its operation with a device as shown in Figs. 1-4.

Fig. 9 shows the construction and operation of the safety means as used in the casing of Figs. 1 to 8.

Figs. 10 and 11 show schematically the construction of another casing of this invention and its operation with a device as shown in Figs. 1-4.

30

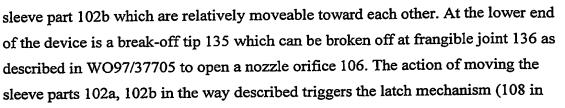
Figs. 12 and 13 show schematically the construction of another casing of this invention and its operation with a device as shown in Figs. 1-4.

Referring to Figs 1-4 the operation of the device 10 disclosed in WO97/37705 is illustrated schematically. The numbering scheme of WO97/37705 is followed in these drawings. The device 10 comprises an upper sleeve part 102a and a lower

20

5

10



5 WO 97/37705, not shown in Figs. 1-4) and causes compressed gas in cylinder 130 to operate an internal ram (111 in WO 97/37705, not shown in Figs 1-4) which drives medicament content 105 in cartridge 103 out through orifice 106. However prior to use the relative movement of sleeve parts 102a and 102b is obstructed by tear-off band 137, being a safety means.

10

25

30

The operation of the device is shown sequentially through Figs. 1-4. Fig 1 shows the pre-use configuration with band 137 in place. In Fig. 2 the break-off tip 135 has been broken off at frangible joint 136, exposing orifice 106. In Fig. 3 the tear off band 137 has been torn off so that relative movement of sleeve parts 102a, 102b is no longer obstructed. In Fig. 4 the orifice 106 has been placed against the skin 11 of

15 the user and pressure has been applied to the cylinder 130 to force sleeve part 102a downwardly relative to sleeve part 102b. As described in WO97/37705 this has "fired" the device and caused the medicament 105 to be injected through the user's skin 11.

Referring to Figs. 5-9 a casing 50 of this invention is shown in a longitudinal sectional view. The casing 50 encloses a device 10 as shown in Figs 1-4. The device 10 is an elongate device, the direction of its longitudinal axis being shown by a dashed line. This direction is also the direction along which the sleeve parts 102a, 102b move relative to each other, and the direction in which medicament content is ejected from the orifice 105.

The casing 50 is generally ellipsoidal elongate in a direction parallel to the longitudinal axis of the device 10 and comprises a first casing part 51 and a second casing part 52. The first casing part 51 and second casing part 52 are joined at a screw thread connection 53. Each casing part 51,52 may itself comprise sub-assemblies fitted together. The casing parts 51,52 are made of plastics material by injection moulding.

Within first casing part 51 the device 10 is supported and held securely by internal supports, bulkheads etc. (not shown but the construction of which will be apparent to those skilled in the art). In particular the device 10 is held within first

casing part 51 such that device 10 is non-rotatable relative to part 51 about an axis parallel to the long axis of casing 51,52.

The tear-off band 137 shown in Figs. 1-4 is not present on the device 10. In its place is a safety means 54 comprising a collar which fits around the cartridge 103 and the sleeve parts 102a,102b. The construction of part 54 is shown in more detail in Fig. 9. As seen in Fig. 9A being a cross section through the collar 54 and device 10 at line A- - A in Fig. 1, and Fig. 9B being a longitudinal part sectional view through the collar 54 and immediately adjacent part of device 10, at right angles to the line A - A of Fig. 9A, the part 54 comprises a collar 541 of cross sectional dimensions greater than that of sleeve parts 102a and 102b, which surrounds cartridge 103 and the immediately adjacent parts of sleeve parts 102a,102b. The part 54 has an obstructer part 542 being a block which when the part 54 is in place around the cartridge 103 as shown in Fig. 5 obstructs any relative longitudinal movement of sleeves 102a and 102b, by fitting longitudinally between them and blocking their relative movement.

The collar 541 is supported in this configuration by resilient spring leaves 543, 544 which bear on the sleeve parts 102a,102b. This is the first configuration of part 54.

15

20

25

Referring to Fig. 6 the second casing part 52 has been rotated relative to first casing part, about the axis of rotation R, thereby unscrewing second casing part 52 from first casing part 51 at screw connection 53 and disconnecting parts 51 and 52. Second casing part 52 has internal parts e.g. internal supports, walls etc. (not shown but the construction of which will be apparent), which bear upon the break-off tip 135. Axis R is parallel to but not co-axial with the longitudinal axis of the part 10, a shearing force is applied to the frangible joint 137, which consequently breaks. The device 10 is now in a configuration corresponding to Fig. 2.

Referring to Fig. 7 an actuator means is provided by a resilient tongue 55, integral with first casing part 51, and which can be inwardly deflected by pressure on an operating button 56. This inward deflection causes means 55 to bear upon the upper surface (as seen in Fig. 9) of the collar 541, and the collar 541 to be consequently moved downwardly against the resilience of springs 543, and the

30 obstructer part 542 to be consequently moved into a position in which it does not obstruct the relative movement of sleeve parts 102a and 102b. This is shown more clearly in Fig. 9C, being the second configuration of part 54. When in this second configuration the first casing part 51 and part 54 may have co-operating means, e.g. snap fit detent means, so that part 54 is retained in this second configuration

independently of pressure applied by part 55. Alternatively, e.g. as a further safety feature, the casing may be constructed so that continued pressure on part 55 is necessary to hold part 54 in this second configuration. The device 10 is now in a configuration corresponding to Fig. 2.

12

5

10

Also as shown in Figs 5 and 6, the second casing part 52 integrally incorporates a cover part 57 comprising a cover flap which covers the actuator button 56 when the second casing part is attached by the screw thread 53 to first casing part 51. This prevents the actuator part 56 from being actuated in the manner shown in Fig. 7 until the second casing part 52 has been unscrewed from first casing part 51 and removed in the downward direction as shown, with the consequence of breaking off the break off tip 135, and thereby causes the user to operate the device 10 in the proper operating sequence as described with reference to Figs. 1-4.

Referring to Fig. 8, the orifice 106 has been placed against the skin 11 of the user and pressure has been applied to the first casing part 51 in the direction toward the skin 11. This pressure is communicated to the injector device 10 to force sleeve part 102a downwardly relative to sleeve part 102b. In a manner corresponding to Fig. 4 this has caused the device 10 to "fire" and to inject medicament 105 through the user's skin 11.

Referring to Fig. 10, another casing 110 of this invention is shown in a side view. The casing 100 incorporates a device 10 as with the casing of Figs. 1-9. The casing 100 comprises first casing part 111 and second casing part 112. The internal construction of the first casing part 111 is analogous to that of first casing part 51, i.e. incorporating a safety means 54 and an actuating means 55, 56 as therein.

Fig. 11 shows a plan view of the casing 110 illustrating more clearly the construction of the part 55 and 56, which is analogous to those of Figs. 1-8.

In the casing 110 the second casing part 112 is mounted on two opposite pivot axles 113, so that part 112 can rotate about the axis between these axles 113, this axis of rotation being perpendicular to the longitudinal axis of the device 10 and of the elongated casing 110, so that part 112 swings in rotation relative to part 111 and follows the arc shown in Fig. 10. As the casing part 112 rotates in this way its internal parts (not shown), such as internal ribs or a cup-shaped holder to hold the break-off tip 135, bear upon the break-off tip 135 and cause the frangible joint 137 to shear analogously to Figs. 2 and 6. As the part 112 continues to rotate along this arc, it

15

have respective co-operating locking means (not shown) by which the part 112 may be initially releasably locked in place in its non-rotated configuration as shown in Fig. 10 before being unlocked to allow the casing part 112 to swing through the arc. Such a locking means may help to prevent accidental break-off of the break off tip 135.

13

The actuator part 55 can then be operated in a manner analogous to the casing of Figs. 5-9 to render the device 10 ready to trigger and "fire".

The orifice 106 can then be placed against the user's skin 11 in a manner analogous to Fig. 8 and pressure can be applied to the first casing part 51 to force sleeve part 102a downwardly relative to sleeve part 102b causing the device 10 to "fire" as in Fig. 4 and 8 to inject medicament 105 through the user's skin 11.

In the device of Figs. 10 and 11 it is of course important that the arc which the second casing part 112 follows allows sufficient of the device 10 to project beyond the lower end as shown of the casing part 111 to allow the orifice 106 to be placed adjacent to the user's skin. This can be arranged by a suitable geometry of the casing 110 to give the second casing part 112 sufficient clearance of the orifice 106 as the part 112 swings in its arc. The second casing part 112 may also be constructed so that a downward (as shown) movement of the second casing part 112 is necessary before

the second casing part 112 can pivot in the manner shown. This can be achieved for example by means of a "keyhole" shaped pivot socket which engages with an
elongate section stub axle which can only rotate when the axle has been moved longitudinally into the wide part of the "keyhole". This can help to provide the clearance between the second casing part 112 and the orifice 106.

The dimensions of the casing parts 111 and 112 may be such that the second casing part 112 may rotate through 180° from the position shown in Figs. 10 and 11 so that it can conveniently be "stowed" at the opposite end of the first casing part 110 to that from which the orifice 106 projects.

It will be apparent that the casing 51,52, 101,102 facilitates the operation of the device 10, and as seen in Fig. 11 can enhance the outward appearance of the casing.

30

25

Referring to Figs. 12 and 13 another casing 120 is shown in schematic longitudinal section. The casing 120 is similar in construction to that of Figs. 5 - 8, having a first casing part 121, and a second casing part (not shown) which is identical to that 52 of Figs 5 - 8 and which is initially connected to casing part 121 by a screw

5

10

thread in an analogous manner. In Fig. 12 the casing 120 is shown with this second casing part removed, i.e. in a configuration analogous to Fig. 7.

The casing 120 incorporates a device 10 as shown in Figs. 1-4. The device 10 has a safety means being a tear-off band 137 analogous to that shown in Figs. 1 and 2. The band 137 has an extension 122 which extends through a window aperture 123 in first casing part 121 to the outside of casing part 121. The extension 122 may be gripped by a user and pulled from outside the casing to thereby remove the band 137 as seen in Fig. 13. The casing 120 is then in a configuration analogous to Fig. 7 and may be used in a manner analogous to Fig. 8. It will be appreciated that band 137 in Fig. 12 may be replaced by other forms of removable obstructer means. As in Figs. 5 - 8 a cover part such as that 57 may cover the extension 122 until the second casing

10

part has been removed.

5

Claims:

5

10

1. A casing for an injector device of the type which comprises

a cartridge containing a medicament for injection and having an orifice at one end thereof through which the medicament may be driven for injection through a patient's skin,

drive means for driving the medicament through the patient's skin a trigger means operable to cause the drive means to act,

a safety means which in a first configuration prevents the drive means from acting and in a second configuration allows the drive means to act,

wherein

the casing is able to enclose the device,

and the casing incorporates an actuator means by which the safety means of an
injector device enclosed therein can be brought from its first configuration into its second configuration.

A casing according to claim 1 wherein the actuator means may be accessed by a user from outside the casing, so that the user can bring the safety means of an
 injector device enclosed therein into its second configuration from outside the casing.

3. A casing according to claim 1 or 2 wherein the actuator means has a part exposed to the outside of the casing and accessible to the user, and to which part the user may apply operating force to bring the safety means into its second configuration.

4. A casing according to claim 3 wherein the actuating means is constructed to bear upon the safety means and thereby apply actuating force to the safety means to bring the safety means into its second configuration.

30

25

5. A casing according to claim 4 wherein the actuator means comprises a button, tongue or lever which the user may press inwardly to cause the actuator means to bear upon the safety means and thereby bring the safety means into its second configuration.

6. A casing according to any one of claims 1 to 5 wherein the actuator means is resiliently connected to the casing such that on application of operating force to the actuator means the actuator means operates against the resilient bias.

7. A casing according to any one of the preceding claims wherein the actuator means is constructed so that after it has brought the safety means into its second configuration, the actuator means give a visible indication that this has happened.

10 8. A casing according to any one of the preceding claims having retaining means to retain the safety means of an enclosed injector device in its second configuration after the safety means has been brought into its second configuration.

9. A casing according to claim 1 wherein the actuator means comprises a
15 window in the casing through which the safety means may be actuated.

10. A combination of:

a casing according to any one of the preceding claims and enclosed within the casing;

20 an injector device of the type which comprises a cartridge containing a medicament for injection and having an orifice at one end thereof through which the medicament may be driven for injection through a patient's skin, drive means for driving the medicament through the patient's skin, a trigger means operable to cause the drive means to act, and a safety means which in a first configuration prevents the drive means from acting and in a second configuration allows the drive means to act.

11. A combination according to claim 10 wherein the safety means prevents the drive means from acting in its first configuration by preventing the trigger means from operating.

30

5

12. A combination according to claim 11 wherein the safety means comprises an obstructer part which in the first configuration obstructs, and in the second configuration allows, the movement of a moveable trigger part.

13. A combination according to claim 11 or 12 wherein the safety means is moveable from its first configuration to its second configuration by using the actuator means.

5 14. A combination according to claim 13 wherein the actuating means is adapted to bear upon the safety means and thereby apply actuating force to the safety means to move it.

15. A combination according to any one of claims 10 to 14 wherein the safety
means comprises a collar shaped to at least partly surround the injector device, and moveable from its first configuration into its second configuration in a direction generally perpendicular to the direction in which the medicament is dispensed, the collar incorporating an obstructer part.

15 16. A combination according to any one of claims 10 to 15 wherein the safety means, or at least the obstructer part, is biased to be retained in its first configuration and is movable against this bias into its second configuration.

17. A combination according to claim 11 or 12 wherein the safety means20 comprises a removable obstructer part.

18. A combination according to claim 17 wherein the safety means comprises a tear-off band.

25 19. A combination according to any one of claims 10 to 18 wherein the trigger means is provided by two relatively moveable upper and lower sleeve parts which on relative movement allow the drive means to act, and the safety means comprises an obstructer part which in its first configuration obstructs, and in its second configuration allows, the relative movement of these sleeve parts.

30

20. A combination according to claim 19 wherein the safety means comprises an obstructer part which is brought from its first configuration to its second configuration by a movement of the obstructer part in a direction perpendicular to the direction of relative movement of the two sleeves.

21. A combination according to claim 20 wherein the safety means comprises a collar shaped to at least partly surround the injector device, and moveable from its first configuration into its second configuration in a direction perpendicular to the direction of relative movement of the two sleeves, the collar incorporating an obstructer part which in the first configuration is situated between the two sleeves to obstruct the relative movement, and in the second configuration is displaced in a direction perpendicular to the direction of relative movement of relative movement of these sleeves to thereby allow the relative movement of these sleeves.

10

20

25

5

22. A combination according to any one of claims 10 to 21 wherein the safety means has retaining means by which it may be retained in its second configuration.

23. A combination according to any one of claims 10 to 21 wherein the safety
means requires a continuous actuation of the actuator means to retain the safety
means in its second configuration.

24. A casing for enclosing a container of a medicament of the type having an opening at one end through which the medicament may be accessed for dispensing and the opening being closed prior to use by a break-off tip,

the casing comprising relatively moveable first and second casing parts, being a first casing part adapted to hold the container, and a second part adapted to bear upon the break-off tip of a container held by the first casing part as a result of such relative motion to apply a force thereto causing the break-off tip to break off from the container.

25. A casing according to claim 24 wherein the first casing part is elongated along a longitudinal axis, the first casing part is adapted hold the container non rotatably relative thereto, and the second part may move in rotary motion relative to the first

30 part so as to bear on the break-off tip of a container held by the first casing part, and to apply a twisting shearing force to the frangible joint between the break-off tip and the container.

26. A casing according to claim 25 wherein the rotary relative motion is about a rotation axis coaxial with the longitudinal axis, about a rotation axis parallel to but non-coaxial with this longitudinal axis, or about a rotation axis at a non-zero angle to the longitudinal axis.

27. A casing according to claim 26 wherein the first and second casing parts are initially connected together by a screw thread connection, so that unscrewing the connection applies a shear force to break off the tip of a container held by the first casing part, and also separates the first and second casing parts to hereby expose the opening for use.

28. A casing according to claim 25 wherein the rotary relative motion is about a rotation axis transverse to the longitudinal axis so as to snap the frangible joint.

15 29. A casing according to any one of claims 24 to 28, being also a casing according to any one of claims 1 to 9, and wherein the first casing part is adapted to hold a container being an injector device of the type wherein the cartridge has an opening at one end through which the medicament may be dispensed and the opening is closed prior to use by a break-off tip.

20

5

10

30. A casing according to claim 29 wherein the first casing part is adapted to hold the injector device, and the first casing part is elongate and has an end opening, and the second casing part comprises a removable cover for this end opening.

25 31. A casing according to claim 30 wherein the second casing part comprises a cover part over the actuator means which prevents operation of the actuator means until the cover part is removed.

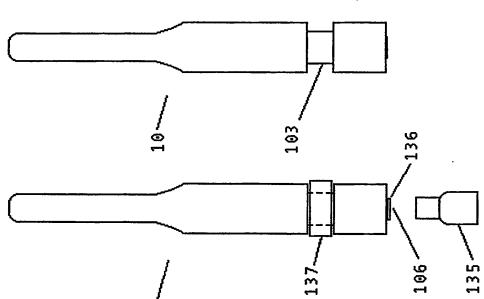
32. A casing according to claim 30 wherein the second casing part incorporates a
30 locking means to lock the actuator means until the second casing part has been removed.

33. A combination of a casing according to any one of claims claim 29 to 32 and an injector device enclosed therein of the type wherein the cartridge has an opening at

one end through which the medicament may be dispensed and the opening is closed prior to use by the break-off tip.

10² 10² 10¹ 10² 10¹ 10²

:



-01

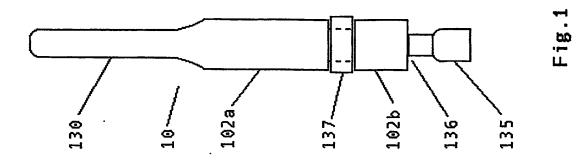
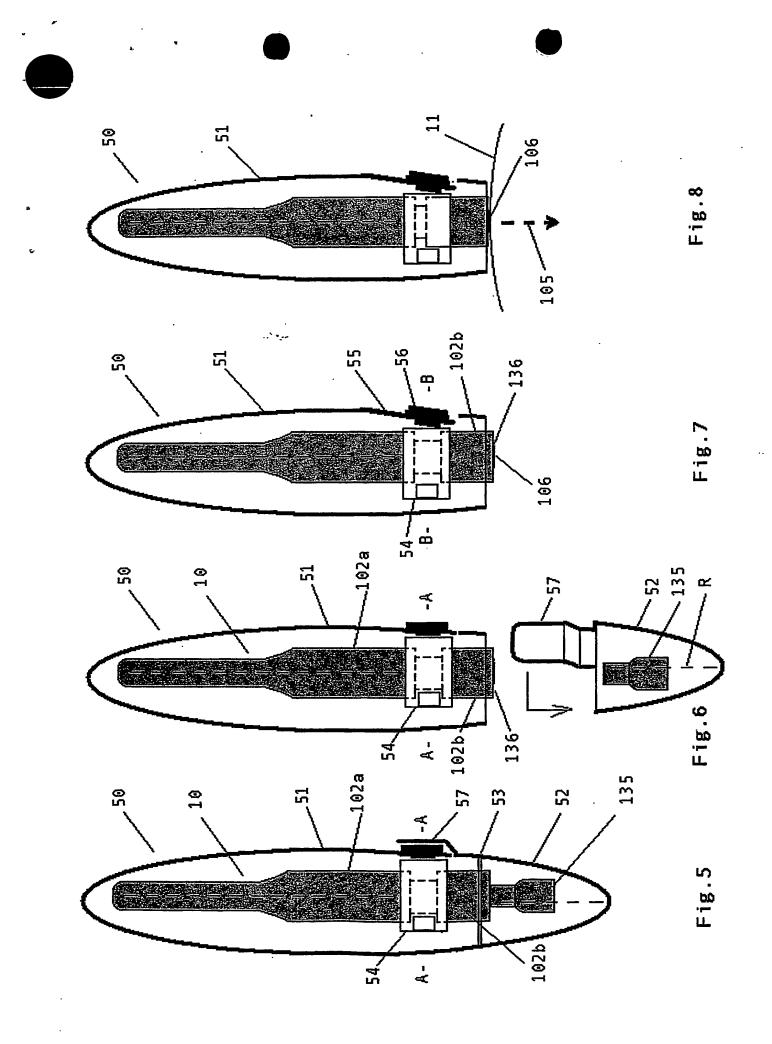
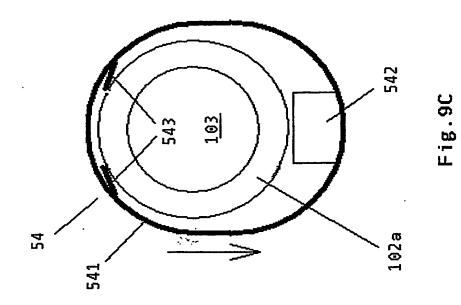


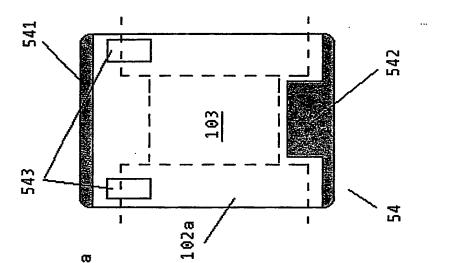
Fig.4

Fig.3

Fig.2







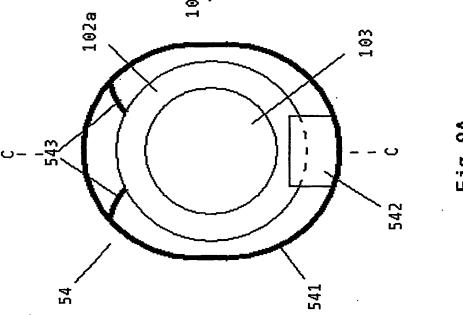
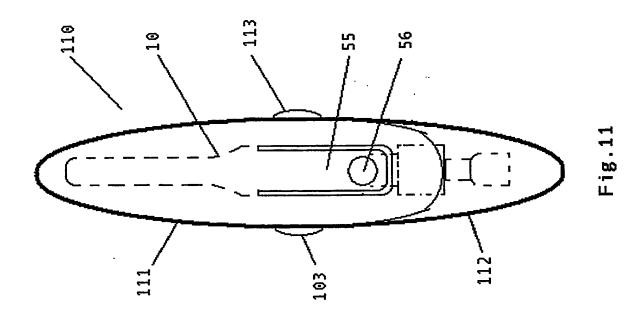
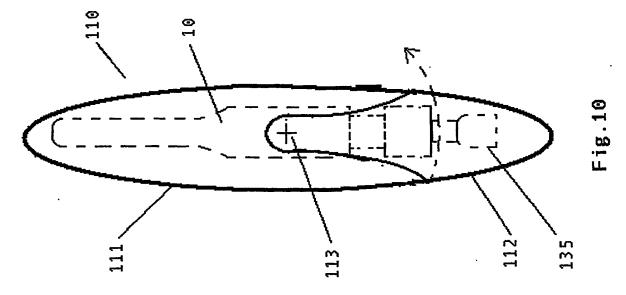


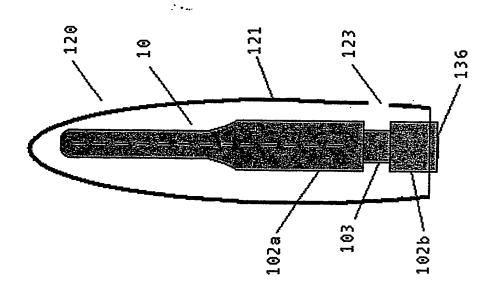
Fig.9B

Fig.9A



. •...





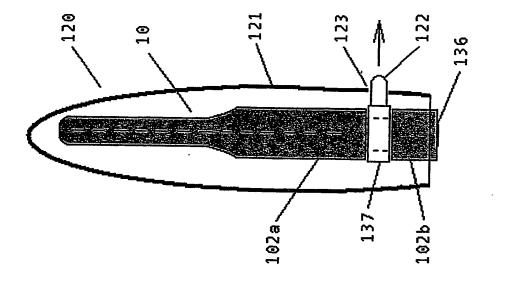


Fig.13

Fig.12

.

This Page is Inserted by IFW Indexing and Scanning Operations and is not part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

BLACK BORDERS

□ IMAGE CUT OFF AT TOP, BOTTOM OR SIDES

A FADED TEXT OR DRAWING

BLURRED OR ILLEGIBLE TEXT OR DRAWING

SKEWED/SLANTED IMAGES

COLOR OR BLACK AND WHITE PHOTOGRAPHS

GRAY SCALE DOCUMENTS

□ LINES OR MARKS ON ORIGINAL DOCUMENT

PREFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY

OTHER: _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.